Advanced Dental Solutions Ltd.
PALTOP®

510(k) SUMMARY

510(k) Number K131451

Applicants Name: Paltop Advanced Dental Solutions Ltd.
Hashita 5
Industrial Park Caesarea 30889, Israel
T +972 4 6271711
F +972 4 6275363

AUG 2 2 2013

Contact Person: Tal Hammer-Topaz
Quality, Regulatory & Clinical Manager
Paltop Advanced Dental Solutions Ltd.
Hashita 5
Industrial Park Caesarea 30889, Israel
T +972 5 23 520050
F +972 4 6275363
Email: ~~tal@paltopdental.com~~

Date Prepared: May 13th, 2013

Type of Submission: Special 510(k)

Trade Name: Paltop Dental Sterile Accessories

Classification Name: Implant, Endosseous, Root-form

Common usual name: Dental Implant Accessories

Medical Specialty: Dental

Product Code: DZE, NHA

Device Class: Class II

Regulation Number: 872.3640

Review Panel: Dental Device Panel

Predicate Device:

- Paltop Dental Implant System (Paltop Advanced Dental Solutions Ltd.) cleared under K112795; product code DZE, NHA (Implant, Endosseous, Root-Form).

Intended Use / Indication for Use:

The Paltop Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Device Description:

Paltop Dental Sterile Accessories are packaged is a standard, commonly used in the dental market, blister packaging made out of radiation resistant transparent polyethylene (PET) sealed with medical grade tyvek sheet. The accessories will be sterilized using gamma irradiation.

Paltop Prosthetic Components include a variety of abutments, healing cups and impression coping components having a central bore and a lower mating surface that is configured to mate with the mating surface of the Paltop implant. The Paltop prosthetic components, as other available in the market dental prosthetics are dental components composed either of titanium (Ti6AL4V ELI) or peek.

Paltop surgical instruments consist of a variety of instruments required for dental-surgical and reconstructive procedures including primary and final drills, Key set and adapters. The Paltop surgical instruments, as other available in the market surgical instruments, are composed of stainless still or TI6AL4V ELI.

Substantial Equivalence:

The modification which is the subject of this special 510(k) notification is change of the packaging only: Paltop modified devices will be provided in a sterile blister package. The modification does not alter the intended use, technological

characteristics and mode of operation of the device. Based on the verification and validation testing results and the analysis of the similarities and differences presented in this submission, Paltop Advanced Dental Solutions Ltd believes that the Paltop dental sterile accessories are substantially equivalent to their predicates (K112795) without raising new issues of safety or effectiveness.

Non Clinical Tests:

Risk analysis process was conducted to assess the impact of the modification of the device. Gamma radiation sterilization validation and shelf life validation were performed. Other performance testing and validations conducted for Paltop's original components (Fatigue, steam sterilization validation) were shown to be applicable to the modified device. Bench testing and validations demonstrates that Paltop dental sterile accessories are substantially equivalent to predicate devices and do not raise new issues of safety or effectiveness.

Clinical Tests:

N/A

Summary:

The evaluation of Paltop Dental Sterile Accessories do not raise any additional concerns regarding safety and effectiveness of the device and therefore Paltop Advanced Dental Solutions Ltd. believes it may be considered as substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

Paltop Advanced Dental Solutions, Limited
Mr. Tal Hamer-Topaz
Quality, Regulatory & Clinical Manager
5 Hashita Street
Industrial Park
CAESAREA, ISRAEL 30889

Re: K131451
Trade/Device Name: PALTOP Dental Sterile Accessories
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: July 28, 2013
Received: July 31, 2013

Dear Mr. Hamer-Topaz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PALTOP

Indications for Use

510(k) Number (if known): K131451

Device Name:

PALTOP Dental Sterile Accessories

Indications for Use:

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Prescription Use __V_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2013.08.22 08:26:44 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K131451